

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC,

Plaintiff,

V.

BOSTON SCIENTIFIC CORPORATION

Defendant.

C.A. No.: _____

DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff Edwards Lifesciences LLC (“Edwards Lifesciences”), for its Complaint against Defendant Boston Scientific Corporation (“Boston Scientific”), alleges as follows:

I. PARTIES

1. Plaintiff Edwards Lifesciences is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at One Edwards Way, Irvine, California 92614.

2. Defendant Boston Scientific is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 300 Boston Scientific Way, Marlborough, Massachusetts 01752.

II. JURISDICTION AND VENUE

3. This is an action for patent infringement arising under the patent laws of the United States of America, Title 35, United States Code. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. Boston Scientific is engaged in the business of manufacturing, selling, offering for sale, and/or importing the Watchman Left Atrial Appendage (“LAA”) Closure Device, the

Watchman Delivery System, and the Watchman Access System (collectively, the “Accused Product”) in the United States, including within this District.

5. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b), because Boston Scientific has committed acts of infringement in this District and is incorporated in this District.

6. Boston Scientific is subject to this Court’s personal jurisdiction because it is incorporated in this District.

III. THE PATENTS-IN-SUIT

7. On December 19, 2000 the United States Patent and Trademark Office issued United States Patent No. 6,162,168 (“the ’168 Patent”) entitled “Heart Wall Tension Reduction Apparatus,” a true and correct copy of which is attached as Exhibit 1.

8. Edwards Lifesciences is the assignee of all rights to the ’168 Patent, including the exclusive right to sue for and recover all past and present damages for infringement of the ’168 Patent.

9. On April 13, 2010, the United States Patent and Trademark Office issued United States Patent No. 7,695,425 (“the ’425 Patent”) entitled “Heart Wall Tension Reduction Apparatus and Method,” a true and correct copy of which is attached as Exhibit 2.

10. Edwards Lifesciences is the assignee of all rights to the ’425 Patent, including the exclusive right to sue for and recover all past, present, and future damages for infringement of the ’425 Patent.

11. The ’168 Patent and the ’425 Patent are collectively referred to herein as the Asserted Patents.

IV. COUNT 1 – DIRECT INFRINGEMENT OF THE '168 PATENT

12. Edwards Lifesciences incorporates paragraphs 1 through 11 as though fully set forth herein.

13. Upon information and belief, Boston Scientific has made, used, sold, offered for sale, and/or imported the Accused Product into the United States since at least March 2015, including within this District.

14. Boston Scientific has directly infringed at least Claim 29 of the '168 Patent either literally or under the doctrine of equivalents by manufacturing, selling, offering for sale, and/or importing the Accused Product, in violation of 35 U.S.C. § 271(a).

15. Claim 29 of the '168 patent states:

A device for treatment of a heart, the device comprising:

a static member configured to be positioned adjacent portions of a wall of a heart chamber; and

an anchoring mechanism coupled to the member to engage the wall of the heart chamber;

wherein the device is configured to alter a shape of the chamber during at least a portion of a cardiac cycle such that the portions of the wall remain in a non-contacting relationship.

16. By way of example, and not limitation, the Accused Product's direct infringement of Claim 29 of the '168 Patent is described below.

17. The Accused Product is a device for treatment of a heart that includes a static member configured to be positioned adjacent portions of a wall of a heart chamber. For

example, the Watchman LAA Closure Device has a nitinol frame that is configured to be positioned adjacent to at least a wall of the left atrium.

18. The Accused Product includes an anchoring mechanism coupled to the static member to engage the wall of the heart chamber. For example, the Watchman LAA Closure Device has fixation anchors that are coupled to the nitinol frame and engage at least a wall of the left atrium.

19. The Accused Product is configured to alter a shape of the chamber during at least a portion of a cardiac cycle such that the portions of the wall remain in a non-contacting relationship. For example, on information and belief, the Watchman LAA Closure Device when implanted presses against at least one wall of the left atrium thereby altering the shape of the heart chamber during at least a portion of the cardiac cycle such that the portions of the wall remain in a non-contacting relationship.

20. Edwards Lifesciences has been damaged by Boston Scientific's infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

V. COUNT 2 – INDUCED INFRINGEMENT OF THE '425 PATENT

21. Edwards Lifesciences incorporates paragraphs 1 through 20 as though fully set forth herein.

22. Boston Scientific has induced infringement of the '425 Patent under 35 U.S.C. § 271(b) by, for example, inducing its customers to use the Accused Product in a manner that constitutes direct infringement of the '425 Patent during the term of the '425 Patent, at least by instructing its customers to perform a method of using the Accused Product that constitutes direct infringement of the '425 Patent.

23. The method of using the Accused Product, for example the method of use described on at least pages 13 and 14 of the Watchman Directions for Use (attached hereto as Exhibit 3), infringes, either literally or under the doctrine of equivalents, one or more claims of the '425 Patent, including at least Claim 1.

24. Claim 1 of the '425 Patent states:

A surgical procedure comprising:

advancing an elongate member towards a target location on a patient's heart, wherein the

elongate member includes a proximal end, a distal end, and a lumen extending therebetween;

inserting the distal end of the elongate member through a heart wall and into a heart chamber;

introducing an instrument and an element through the elongate member for installing the element; and

installing the element in contact with first and second spaced apart portions of the heart, wherein the element traverses a chamber of the heart, and wherein all portions of the heart chamber remain in non-contacting fluid communication when the element is installed.

25. By way of example, and not as a limitation, the method of using the Accused Product, as described in at least Exhibit 3, constitutes direct infringement of Claim 1 of the '425 Patent as described below.

26. The method of using the Accused Product is a surgical procedure that includes advancing an elongate member, for example the Watchman Access Sheath, toward a target location on a patient's heart, for example, the intra-atrial septum.

27. The Accused Product includes a proximal end, a distal end, and a lumen extending therebetween. For example, the Watchman Access Sheath includes a proximal end, a distal end, and a lumen extending therebetween.

28. The method of using the Accused Product includes inserting the distal end of the elongate member through a heart wall and into a heart chamber. For example, the method of using the Accused Product includes inserting the distal end of the Watchman Access Sheath through the intra-atrial septum and into the left atrium.

29. The method of using the Accused Product includes introducing an instrument, for example the Watchman Delivery Catheter, and an element, for example the Watchman LAA Closure Device, through the Watchman Access Sheath, for installing the Watchman LAA Closure Device.

30. The method of using the Accused Product includes installing the element, for example the Watchman LAA Closure Device, in contact with first and second spaced apart portions of the heart, wherein the Watchman LAA Closure Device traverses a chamber of the heart, for example the left atrium, and wherein all portions of the left atrium remain in non-contacting fluid communication when the Watchman LAA Closure Device is installed.

31. Therefore, by way of example, and not as a limitation, practicing the method of using the Accused Product as described in at least Exhibit 3 constitutes direct infringement of at least Claim 1 of the '425 Patent under 35 U.S.C. § 271(a).

32. Upon information and belief, Boston Scientific sells the Accused Product to its customers.

33. Upon information and belief, Boston Scientific's customers practice the method of use for the Accused Product described and as instructed by Boston Scientific in at least Exhibit 3.

34. Upon information and belief, Boston Scientific's customers directly infringe at least Claim 1 of the '425 Patent by using the Accused Product as directed that they acquire from Boston Scientific.

35. Upon information and belief, Boston Scientific had actual knowledge of the '425 Patent prior to the filing of this Complaint. For example, on February 19, 2015 in the prosecution of U.S. Patent No. 9,730,701, one of Boston Scientific's subsidiaries cited the '425 Patent in an information disclosure statement to the United States Patent and Trademark Office. U.S. Patent No. 9,730,701 purportedly relates to "percutaneous medical devices for implantation into the left atrial appendage (LAA) of a heart."

36. Upon information and belief, Boston Scientific knew that its customers would infringe the '425 Patent by using the Accused Product during the term of the '425 Patent. For example, Boston Scientific provides Exhibit 3 to its customers with the Accused Product. At least pages 13 and 14 of Exhibit 3 instruct the customer to perform a method of using the Accused Product that would constitute direct infringement of at least Claim 1 of the '425 Patent.

37. Upon information and belief, Boston Scientific had the specific intent to induce and did induce its customers to infringe the '425 Patent under 35 U.S.C. § 271(b), by, for example, causing its customers to use the Accused Product in a manner that constitutes direct infringement of at least Claim 1 of the '425 patent during the term of the '425 Patent, including by providing marketing materials and instructions for use, such as for example the Directions for

Use (Exhibit 3), to its customers that instruct the customers to perform a method of using the Accused Product that infringes at least Claim 1 of the '425 Patent.

38. Boston Scientific's actions constitute willful and intentional infringement of the '425 Patent. Boston Scientific induced infringement of the '425 Patent with reckless disregard of Edwards Lifesciences' patent rights. Boston Scientific knew of the '425 Patent by, for example, its prosecution of U.S. Patent No. 9,730,701. After obtaining knowledge of the '425 Patent, Boston Scientific continued to sell the Accused Product and instruct its customers to use the Accused Product via a method that infringes the '425 Patent. Boston Scientific knew, or it was so obvious that Boston Scientific should have known, that the actions it induced its customers to take constituted acts of infringement of the '425 Patent.

39. Edwards Lifesciences has been damaged by Boston Scientific's infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

VI. COUNT 3 – CONTRIBUTORY INFRINGEMENT OF THE '425 PATENT

40. Edwards Lifesciences incorporates paragraphs 1 through 39 as though fully set forth herein.

41. Boston Scientific has contributed to the infringement of the '425 Patent under 35 U.S.C. § 271(c) by, for example, offering for sale, selling, and/or importing the Accused Product for use in practicing the patented process of the '425 Patent, where the Accused Product constitutes a material part of the invention, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and is known by Boston Scientific to be especially adapted for use in an infringement of the '425 Patent. As a result, the Accused Product has been used by Boston Scientific's customers and users in a manner that directly infringes at least claim

1 of the '425 Patent, as set forth, for example, in Paragraphs 23-34 above, which are incorporated as if fully set forth herein.

42. Upon information and belief, Boston Scientific had actual knowledge of the '425 Patent prior to the filing of this Complaint for at least the reasons set forth in Paragraph 35 above, which is incorporated as if fully set forth herein.

43. Upon information and belief, Boston Scientific knew that selling the Accused Product would lead to direct infringement of the '425 Patent by its customers. For example, Boston Scientific provides Exhibit 3 to its customers with the Accused Product. At least pages 13 and 14 of Exhibit 3 instruct the customer to perform a method of using the Accused Product that would constitute direct infringement of at least Claim 1 of the '425 Patent.

44. Boston Scientific's actions constitute willful and intentional infringement of the '425 Patent. Boston Scientific contributed to the infringement of the '425 Patent with reckless disregard for Edwards Lifesciences' patent rights. Boston Scientific knew of the '425 Patent by, for example, its prosecution of U.S. Patent No. 9,730,701. After obtaining knowledge of the '425 Patent, Boston Scientific continued to sell the Accused Product knowing that its customers use of the Accused Product via the method described in, for example, Exhibit 3 would constitute infringement of the '425 Patent. Boston Scientific knew that the Accused Product has no other substantial non-infringing use.

45. Edwards Lifesciences has been damaged by Boston Scientific's infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

VII. DEMAND FOR JURY TRIAL

46. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Edwards Lifesciences requests a trial by jury of all issues so triable.

VIII. PRAYER FOR RELIEF

WHEREFORE, Edwards Lifesciences requests the following relief:

47. A judgment in favor of Edwards Lifesciences that Boston Scientific has directly infringed one or more claims the '168 Patent;

48. A judgment in favor of Edwards Lifesciences that Boston Scientific has induced the infringement of one or more claims of the '425 Patent;

49. A judgment in favor of Edwards Lifesciences that Boston Scientific's inducement of the infringement of the '425 Patent has been willful;

50. A judgment in favor of Edwards Lifesciences that Boston Scientific has contributed to the infringement of one or more claims of the '425 Patent;

51. A judgment in favor of Edwards Lifesciences that Boston Scientific's contributory infringement of the '425 Patent has been willful;

52. A ruling that this case is exceptional under 35 U.S.C. § 285;

53. A judgment and order requiring Boston Scientific to pay Edwards Lifesciences damages adequate to compensate for infringement under 35 U.S.C. § 284, which damages in no event shall be less than a reasonable royalty for the use made of the inventions of the Asserted Patents, including supplemental damages for any continuing post-verdict infringement up until the entry of judgment, with an accounting, as needed, pre- and post-judgment interest and costs, including expenses and disbursements;

54. A judgment and order requiring Boston Scientific to pay Edwards Lifesciences treble damages for willful infringement under 35 U.S.C. § 285; and

55. Any and all such further necessary relief as the Court may deem just and proper.

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